



**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**45 CFR Part 89**

**Interim Guidance for Implementation of the Organizational Integrity of Entities Implementing Programs and Activities under the Leadership Act**

**AGENCY:** Office of Global Affairs (OGA), Department of Health and Human Services (HHS).

**ACTION:** Notice of interim guidance.

**SUMMARY:** This document provides interim guidance on the implementation of section 301(f) of the Leadership Act in light of the Supreme Court's decision in *Agency for Int'l Dev. v. Alliance for Open Soc'y Int'l, Inc.*, 133 S. Ct. 2321 (2013) ("AOSI decision"). While HHS awarding agencies have implemented the AOSI decision since its issuance, this document serves to clarify HHS policy. HHS is also currently developing an amendment to its regulations listed under "Organizational Integrity of Entities Implementing Programs and Activities under the Leadership Act" to ensure consistency with the decision. HHS has been coordinating its implementation activities with the Department of State, Office of the Global AIDS Coordinator

(OGAC) and with the United States Agency for International Development (USAID). While issued through OGA, this guidance represents the views of the various agencies within HHS that issue awards with Leadership Act HIV/AIDS funds, namely, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Health Resources and Services Administration.

**DATES:** Effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** Erin Eckstein, Office of Global Affairs, Department of Health and Human Services, Room 639H, 200 Independence Avenue SW, Washington DC 20201, Telephone (202) 205-3569.

**SUPPLEMENTARY INFORMATION:**

**Background:**

Section 301(f) of the Leadership Act, subject to limited exceptions, prohibits the use of Leadership Act HIV/AIDS funds "to provide assistance to any group or organization that does not have a policy explicitly opposing prostitution and sex trafficking." Interpreting the policy requirement, in 2010, HHS provided, through rulemaking, that, unless exempted through

statute, contractors, grantees, applicants or awardees who receive Leadership Act funds for HIV/AIDS programs directly or indirectly from HHS must “agree that they are opposed to the practices of prostitution and sex trafficking.” 45 CFR 89.1(b)<sup>1</sup>.

In 2005, section 301(f) was challenged as unconstitutional, and in 2013, the Supreme Court affirmed a Second Circuit decision that upheld a lower court’s preliminary injunction prohibiting the application of the policy requirement to domestic (United States) organizations, finding that such a condition of federal funding violates the First Amendment. Consistent with the Supreme Court’s decision, the requirement to have a specific policy as stated in section 301(f) no longer applies to U.S. organizations.

In coordination with OGAC and USAID, HHS has ceased applying the policy pledge requirement to U.S. organizations, whether they are prime recipients or subrecipients of Leadership Act HIV/AIDS funds. However, the requirement remains applicable to foreign organizations.

**Guidance:**

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<sup>1</sup> Title 45, Subtitle A, Subchapter A, Part 89 in the Electronic Code of Federal Regulations (<http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=70aabffde1bdb20e22fdde1663cbbaa&ty=HTML&h=L&r=PART&n=45y1.0.1.1.46>).

U.S. organizations that are prime recipients or subrecipients of Leadership Act HIV/AIDS funds are not required to have a policy explicitly opposing prostitution and sex trafficking. The Department of Health and Human Services applies the requirement of the Leadership Act that organizations have a policy explicitly opposing prostitution and sex trafficking only to foreign organizations, including foreign affiliates of United States organizations, whether prime recipients or subrecipients, unless exempted by the Act or implementing regulations. See, e.g., 48 CFR 352.270-8 (2010).

HHS is currently developing an amendment to its regulation at 45 CFR part 89 to reflect the *AOSI* decision and HHS's implementation of that decision with respect to U.S. organizations and foreign organizations that are recipients of Leadership Act HIV/AIDS funds.

**AUTHORITY:** 45 CFR part 89; Section 301(f) of the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003, Public Law 108-25, as amended, 22 U.S.C. 7601-7682 ("Leadership Act").

**Dated:** September 11, 2014.

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Jimmy Kolker,  
Assistant Secretary for Global,  
Affairs, Office of Global Affairs.

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